

penalty at an amount sufficiently close to or at the maximum permitted by § 150.315 to reflect that fact. HCFA considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 150.323 Determining the amount of penalty—other matters as justice may require.

HCFA may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 150.325 Settlement authority.

Nothing in §§ 150.315 through 150.323 limits the authority of HCFA to settle any issue or case described in the notice furnished in accordance with § 150.307 or to compromise on any penalty provided for in §§ 150.315 through 150.323.

§ 150.341 Limitations on penalties.

(a) *Circumstances under which a civil money penalty is not imposed.* HCFA does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. HCFA also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to HCFA's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 150.343 Notice of proposed penalty.

If HCFA proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the HIPAA requirements that HCFA has determined that the responsible entity violated.

(b) A description of any complaint or other information upon which HCFA based its determination, including the basis for determining the number of affected individuals and the number of days for which the violations occurred.

(c) The amount of the proposed penalty as of the date of the notice.

(d) Any circumstances described in §§ 150.317 through 150.323 that were considered when determining the amount of the proposed penalty.

(e) A specific statement of the responsible entity's right to a hearing.

(f) A statement that failure to request a hearing within 30 days permits the assessment of the proposed penalty without right of appeal in accordance with § 150.347.

§ 150.345 Appeal of proposed penalty.

Any entity against which HCFA has assessed a penalty may appeal that penalty in accordance with § 150.401 *et seq.*

§ 150.347 Failure to request a hearing.

If the responsible entity does not request a hearing within 30 days of the issuance of the notice described in § 150.343, HCFA may assess the proposed civil money penalty, a less severe penalty, or a more severe penalty. HCFA notifies the responsible entity in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment. The responsible entity has no right to appeal a penalty with respect to which it has not requested a

§ 150.347

hearing in accordance with § 150.405 unless the responsible entity can show good cause, as determined under § 150.405(b), for failing to timely exercise its right to a hearing.

APPENDIX A TO SUBPART C OF PART 150—EXAMPLES OF VIOLATIONS

This appendix lists actions in the group and individual markets for which HCFA may impose civil money penalties. This list is not all-inclusive.

NOTE 1: All cross-references to sections of the Code of Federal Regulations are cross-references to sections in parts 144, 146, or 148 of this subchapter.

NOTE 2: Except as otherwise expressly noted, all references to non-Federal governmental plans refer to non-Federal governmental plans that are *not* exempt from HIPAA requirements (as defined in § 150.103) under section 2721(b)(2) of the PHS Act and § 146.180.

I. Basis for Imposition of Civil Money Penalties—Actions in the Group Market

a. Failure to comply with the limitations on pre-existing condition exclusions (§ 146.111).

Violations of the limitations on pre-existing condition exclusions, set forth in § 146.111, includes those circumstances in which a non-Federal governmental plan or health insurance issuer offering group health insurance coverage does the following:

(1) Imposes a preexisting condition exclusion period that exceeds 12 months or, in the case of a late enrollee, 18 months, from the enrollment date (the first day of coverage or the first day of the waiting period, if any).

(2) Fails to reduce a pre-existing condition exclusion period by creditable coverage as provided in §§ 146.111(a)(1)(iii) and 146.113.

(3) Imposes a pre-existing condition exclusion period without first giving the two written notices required in §§ 146.111(c) and 146.115(d). The first notice is a general notice to all plan participants of the existence and terms of any pre-existing condition exclusion under the plan, and the rights of individuals to demonstrate creditable coverage. The notice should explain the right of an individual to request a certificate from a previous plan or issuer, if necessary, and include a statement that the current plan or issuer will assist in obtaining a certificate from a previous plan or issuer, if necessary. The second notice is required to be sent to any individual who has presented evidence of creditable coverage, and to whom a pre-existing condition exclusion period will be applied. This second notice informs the individual of the plan's determination of any pre-existing condition exclusion period, the basis for such determination, a written explanation of any

45 CFR Subtitle A (10–1–99 Edition)

appeals procedures established by the plan or issuer, and a reasonable opportunity to submit additional evidence of creditable coverage.

(4) Treats pregnancy as a pre-existing condition, as prohibited by § 146.111(b)(4). For example, an issuer may not refuse to pay for prenatal care and delivery effective with the date maternity coverage began because the individual did not have maternity coverage at the time the pregnancy began.

(5) Imposes a pre-existing condition exclusion with regard to a child who enrolls in a group health plan within 30 days of birth, adoption, or placement for adoption.

(6) Imposes a pre-existing condition exclusion with regard to a child who was enrolled in another group health plan within 30 days of birth, adoption, or placement for adoption and who does not experience significant break in coverage.

(7) Uses a pre-existing condition look-back period that exceeds the six-month period ending on the enrollment date in violation of § 146.111(a)(1) of this chapter.

(8) Determines whether a pre-existing condition exclusion applies by using a standard other than whether medical advice, diagnosis, care, or treatment was actually recommended or received during the look-back period. A determination that a reasonably prudent person would or should have sought medical care for the condition is an unacceptable standard by which to determine whether a pre-existing condition exclusion applies.

(9) Uses genetic information as part of the definition of pre-existing condition in the absence of a diagnosis of the condition related to the genetic information.

(10) Otherwise fails to comply with § 146.111.

b. Failure to comply with the provisions relating to creditable coverage (§ 146.113).

Failure to comply with the § 146.113 rules relating to creditable coverage includes those circumstances in which a non-Federal governmental plan or issuer offering group health insurance coverage does the following:

(1) Fails to treat all forms of coverage listed in § 146.113(a) as creditable coverage.

(2) Counts creditable coverage in a manner inconsistent with the standard method described in § 146.113(b) or the alternative method described in § 146.113(c), if it elects to use the alternative method.

(3) Treats an individual with fewer than 63 consecutive days without creditable coverage as having a significant break in coverage in violation of § 146.113(b)(2)(iii).

(4) Takes either a waiting period or an affiliation period into account when calculating a significant break in coverage, as prohibited by § 146.113(b)(2)(iii).

(5) Otherwise fails to comply with § 146.113.